

**REMARKS**

Favorable reconsideration of this application in light of the amendments to the Specification reflected above and Sequence Listing provided herewith is respectfully requested.

No claims having been canceled or added, the Applicants respectfully submit that claims 1-28 remain properly under consideration in this application.

The Applicants further note that no errors were detected during verification of the computer readable format file from the enclosed CD using Checker 4.4.0.

**Species Election**

The Examiner is also requiring an election of species between the disclosed species of antibody for prosecution on the merits. Currently, claims 1-5 and 22-24 are deemed generic with respect to this election.

The Examiner is also requiring an election of species between disclosed species of particle forming proteins. Currently, claims 1, 8-13 and 18-21 are deemed generic with respect to this species election.

The Examiner is also requiring an election of species between disclosed species of encapsulated substances. Currently claim 1 is deemed generic with respect to this species election.

**Applicants' Species Election**

With respect to the disclosed species of antibody, the Applicants elect, with traverse, the “cancer-specific antibody” as recited in claim 2 for prosecution on the merits. The Applicants submit that claims 1-5 and 22-24 remain generic with respect to this election.

With respect to the disclosed species of particle forming proteins, the Applicants elect, with traverse, the “modified hepatitis B virus surface-antigen protein” as recited in claim 8. The Applicants submit that claims 1-13 and 18-21 are generic with respect to this species election. The Applicants further submit that the Sequence Listing has been supplemented to include the 72 varieties of “modified hepatitis B virus surface-antigen protein” known to those skilled in the art and would have been recognized by one skilled in the art as encompassed by the original disclosure. The Applicants further submit that the recognition within the art that these proteins comprise a related group would be sufficient suggest that each member of the group would be obvious in light of any other member of the same group.

With respect to the disclosed species of encapsulated substances, the Applicants elect, with traverse, the “thymidine kinase (KSV1tk) gene” derived from simple herpes virus” as recited in claim 15. The Applicants submit that at least claims 1 and 14 are generic with respect to this species election. The Applicants further submit that the Sequence Listing has been supplemented to include the 71 varieties of “thymidine kinase (KSV1tk) gene” known to those skilled in the art and would have been recognized by one

skilled in the art as encompassed by the original disclosure. The Applicants further submit that the recognition within the art that these genes comprise a related group would be sufficient suggest that each member of the group would be obvious in light of any other member of the same group.

### **Arguments in Support of Traverse**

Although the Applicants agree with the Examiner that peptide and protein sequences are typically distinct from one another, the Applicants suggest that no logical basis has been established for distinguishing between a series of amino acids and a corresponding (and much longer) sequence of bases. Accordingly, the Applicants maintain that no statutory or regulatory basis has yet been identified for the contention that the only “reasonable” number of protein and peptide sequences is 1. Absent such a basis, the Applicants maintain that they are entitled to examination of a reasonable number of sequences.

The Applicants contend that the “cancer-specific antibody” limitation is a functional limitation that encompasses a variety of antibodies and is not generally amenable to the requested specifies election. Indeed, as will be appreciated by those skilled in the art, even a single type of cancer may be characterized by a range of surface proteins that will tend to change as the tumor grows and that the antibodies targeting these proteins cannot, therefore, easily or realistically be characterized by a single sequence.

Accordingly, the Applicants maintain that the present functional claim language is sufficiently precise to define the metes and bounds of the claim to one of ordinary skill in the art. The Applicants submit, therefore, that limitation to a single sequence is inappropriate and that the requirement should be reconsidered and withdrawn.

Finally, the Applicants note that MPEP § 803 provides that where the search and examination of all the claims in an application can be made without “serious burden,” the examiner *must* examine the claims on the merits, even if they include claims to independent or distinct inventions. The Applicants note that the automated searching tools, in conjunction with the provision of the disclosed amino acid and nucleotide sequences in CRF tends to remove any “serious burden” with regard to the searching and examination inventions involving sequences, particularly when those sequences are recognized collectively by those skilled in the art.

In this instance, the Applicants contend that both the “modified hepatitis B virus surface-antigen protein” and the “thymidine kinase (HSV1tk) gene derived from simple herpes virus” are terms understood by those skilled in the art to correspond to the limited number of sequence listings provided in the updated sequence listing. The Applicants contend, therefore, that these terms are sufficiently distinct, descriptive and searchable whereby no “serious burden” is presented by the present species election.

### CONCLUSION

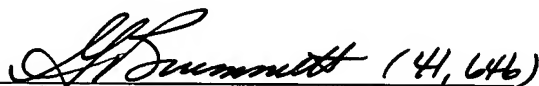
In view of the above remarks and amendments, the Applicants respectfully submit that the present application in condition for examination and allowance. A notice to that effect is respectfully requested.

If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge any underpayment or non-payment of any fees required under 37 C.F.R. §§ 1.16 or 1.17, or credit any overpayment of such fees, to Deposit Account No. 08-0750, including, in particular, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY & PIERCE, P.L.C.

By  (41, 646)

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Enclosure: Copy of Sequence Listing  
Computer Readable Format (CRF) Sequence Listing (CD)  
Statement Under 37 C.F.R. § 1.821(f)